United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

SEP 25 2003

Dr. Frits H. Pluimers
Chief Veterinary Officer
Ministry of Agriculture, Nature Management and Fisheries
Room 4205
Post Office Box 20401
2500 EK The Hague
The Netherlands

Dear Dr. Pluimers:

Enclosed is a copy of the final report of the Food Safety and Inspection Service audit of the Netherlands' meat inspection system conducted from January 15, 2003 through February 12, 2003. Comments by the Netherlands on the draft final audit report have been included in the final audit report.

If you have any questions or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040 or by e-mail at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen

Sally Stratmoen, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Inge Hamid, Agric. Attaché, Royal Netherlands Embassy
Roger Wentzel, Agric. Counselor, US Embassy, The Hague
Norval Francis, Minister/Counselor for Agricultural Affairs, USEU/Brussels
Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the US
Scott Bleggi, Area Officer, FAS
David Young, ITP, AS
Linda Swacina, Deputy Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA
Amy Winton, State Department
Donald Smart, Director, OPEER, FSIS
Clark Danford, Director, IEPS, OIA
Sally Stratmoen, Director, IES OIA
Richard F. Brown, IES, OIA
Steve McDermott, IES, OIA
Country File (Netherlands FY 2003 Jan03)

FINAL

SEP - 4 2003

FINAL REPORT OF AN AUDIT CARRIED OUT IN THE NETHERLANDS COVERING THE NETHERLANDS' MEAT INSPECTION SYSTEM

January 15, 2003 through February 12, 2003

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. INTRODUCTION

2. OBJECTIVE OF THE AUDIT

3. PROTOCOL

4. LEGAL BASIS FOR THE AUDIT

5. SUMMARY OF PREVIOUS AUDITS

6. MAIN FINDINGS
   - 6.1 Legislation
   - 6.2 Government Oversight
   - 6.3 Headquarters Audit

7. ESTABLISHMENT AUDITS

8. LABORATORY AUDITS

9. SANITATION CONTROLS
   - 9.1 SSOP
   - 9.2 EC Directive 64/433

10. ANIMAL DISEASE CONTROLS

11. SLAUGHTER/PROCESSING CONTROLS
   - 11.1 Humane Handling and Slaughter
   - 11.2 HACCP Implementation
   - 11.3 Testing for *Enterobacteriaceae*
   - 11.4 Testing for *Listeria monocytogenes*
   - 11.5 EC Directive 64/433

12. RESIDUE CONTROLS
   - 12.1 FSIS Requirements
   - 12.2 EC Directive 96/22
   - 12.3 EC Directive 96/23

13. ENFORCEMENT CONTROLS
   - 13.1 Daily Inspection
   - 13.2 Testing for *Salmonella*
   - 13.3 Species Verification
   - 13.4 Monthly Reviews
   - 13.5 Inspection System Controls

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority. National Inspection Service for Livestock and Meats.
FSIS	Food Safety and Inspection Service
RVV	National Inspection Service for Livestock and Meat
KvW	Inspectorate for Health Protection and Veterinary Public Health
VWA	The Food and Non-Food Authority
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species

1. INTRODUCTION

The audit took place in the Netherlands from January 15, 2003 through February 12, 2003.

An opening meeting was held on January 15, 2003 in The Hague (Voorburg) with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of the Netherlands meat inspection system.

The auditor was accompanied during the entire audit by representatives from the National Inspection Service for Livestock and Meats and representatives from the regional and/or local inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a follow-up audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of RVV, two regional inspection offices, three district offices, two laboratories, performing analytical testing on United States-destined product, and 10 swine slaughter and processing establishments.

Competent Authority Visits			Comments
Central Competent Authority	RVV	1	
	Regions	2	
	Districts	3	
Laboratories		2	
Meat Slaughter Establishments		6	
Meat Processing Establishments		2	
Cold Storage Facilities		2	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to 10

establishments: six slaughter establishments, two processing establishments and two cold storage facilities. The fourth part involved visits to two government laboratories. Central Laboratory RVV located at Wageningen was conducting analyses of field samples for the presence of *Enterobacteriaceae* and *Salmonella* and Rikilt Laboratory located at Wageningen was conducting analyses of field samples for the Netherlands national residue control program.

Program effectiveness determinations of the Netherlands inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for *Enterobactereacie*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. The Netherlands inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by The Netherlands and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, testing for *Enterobacteriaceae* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for the Netherlands under provisions of the Sanitary/Phytosanitary Agreement.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofo/tsc.

In the audit of October 2001, the following findings were observed:

- Problems with implementation of SSOP.
- Problems with implementation of HACCP.
- Lack of daily inspection.
- Lack of periodic supervisory reviews.
- Lack of pre-shipment reviews.
- Improper selection for *Enterobacteriaceae* sampling
- Inadequate quality assurance programs at government laboratories.
- Inadequate training of inspectors
- Inadequate control of inedible product.

The audit of June 2002 noted the following problems:

- Continuing problems with SSOP and HACCP implementation
- Continuing problems with monthly reviews.
- Problems with sanitary operations in and grounds and pest controls of the establishments.
- Inadequate daily inspection.
- Inadequate enforcement by CCA in approved establishments.
- Inadequate training of inspectors.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that following relevant EC Directives, determined equivalent under the VEA, as mentioned in Section 4 above, have been transposed into Dutch legislation and are being applied in all approved plants, as appropriate.

6.2 Government Oversight

6.2.1 CCA Control Systems

FSIS regulations require that foreign countries that wish to become eligible to export meat to the United States or wish to maintain their current eligibility must be organized and administered by the national government. More specifically, there must be sufficient organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all establishments producing product for export to the United States. Second, the national government must have ultimate control and supervision over the official activities of all employees and licensees. Third, the national government must ensure the assignment of competent, qualified inspectors. Fourth, national inspection officials must have the authority and responsibility to enforce the laws and regulations governing meat inspection. Finally, the country must have adequate administrative and technical support to operate its inspection program.

The organization of the Netherlands' National Inspection Service for Livestock and Meat (RVV) consists of four levels: central, regional, district, and team. In January 2003, RVV was merged with the Inspectorate for Health and Veterinary Public Health (KvW) and a new Food and Non-Food Authority (VWA) was created. The Director of RVV now reports to Director General of VWA. However, RVV will still be responsible for meat inspection services. This is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced. The RVV, with regard to meat inspection, is staffed with approximately 1600 personnel. These personnel are scattered throughout the 12 Provinces of the Netherlands. The boundaries of the five Regional offices correspond to the boundaries established by the Provinces. The Regions are not, however, subject to Provincial rules. The five Regional offices manage 17 Districts in the Netherlands and the District offices manage 48 Teams. Each Team inspects two or more establishments and is supervised by a Team Leader. Each Team Leader supervises two or more Veterinarians-in-Charge, other full time RVV Veterinarians, part-time private practitioners, full-time RVV Meat Inspectors, and non-permanent Assistant Meat Inspectors. Overall, approximately 26 veterinarians and 150 inspectors are tasked with providing direct meat inspection services to establishments that are certified to produce or store products for U.S. consumption. There are generally two levels of employment for inspectors and veterinarians at the District level. These two levels consist of full-time, permanent veterinarians or inspectors and part-time and/or non-permanent practitioners (veterinarians) or assistant meat inspectors.

Some auditors have been delegated responsibility of performing quality audits off U.S. approved establishments. Each of these auditors has his/her own checklist and report format developed from based on RVV instructions and/or his/her own experience. Most Regions used the Team Leaders to certify U.S. establishments. In addition, a few trained auditors throughout the CCA perform process systems audits, primarily auditing establishments' HACCP systems.

Since 2002, specialized personnel had been added to the field teams to enhance the objective to increase CCA supervision and control of inspection personnel and activities at the establishment level. Also, specialized personnel were added to the teams to help

the Team Leaders in auditing. Two or more of the three specialized positions had also been added per team. These positions are senior inspector or foreman, technical-administrative inspector, and auditor for inspection control and auditing. These team-based auditors have responsibility of performing audits of the process systems of establishments, particularly the SSOP and HACCP systems.

In addition, the Regional and District offices have been staffed with specialists, staffing planners, administrative personnel, and auditors to assist in implementing of inspection system. Regional offices have a Director and a Deputy Director, one of which is a Veterinarian. The other individual is an accountant or an economist or an administrator by training and experience. This process broadens the information pool available throughout the RVV.

In response to the previous FSIS audits and as a result of their internal audits, the CCA reduced the number of U.S. certified establishments from 19 to 14 by voluntary surrendering of their certified status. One establishment was delisted by RVV because it did not meet the requirements; four voluntarily surrendered their certification.

6.2.2 Ultimate Control and Supervision

As indicated above, the RVV has the legal authority to supervise the activities of the Regional offices, the Regional offices have the authority to supervise the activities of the District offices, and the District offices have the authority to supervise the activities of the Teams. Through this linear system, regulations and instructions are implemented throughout the country. However, the degree to which one office supervises another office and their activities can vary considerably in the detailing of specific information and in the level of personal contact with the individuals being supervised. To begin with, information is normally distributed via a CCA Intranet. This Intranet contains all of the applicable regulations and instructions; with new and updated instructions being identified as such. All applicable regulations are rendered or incorporated into instructions, as needed, by the CCA.

Regulations from non-EU countries are considered bilateral agreements by the CCA. These regulations, when introduced, are translated into Dutch and used to develop new or revised instructions for field personnel to follow. EU Directives are translated into Dutch and incorporated into Dutch legislation. The Dutch legislation is then used to develop new or revised instructions. Checklists are normally developed from one or more instructions, either in part or in total, to ensure that inspection personnel account for all the provisions of the instructions. The FSIS auditor verified through audits of the regional and District offices that instructions and checklists were received by these offices. The Central office ensures that regulations are properly developed into instructions and, where applicable, into checklists. Regulations are rarely compared to checklists that are developed at the lower levels for specific purposes. Regional and District offices, with Team Leader assistance, are primarily responsible for ensuring that instructions and national checklists are used appropriately. Team Leaders and each resident Veterinarian-in-charge (VIC) are primarily responsible for ensuring that veterinarians and inspectors carry out the functions noted on the national and locally developed checklists. However, there is very little direct field supervision by the Central

office or by the Regional Directors or District Heads to verify the full implementation of legislation and regulatory instructions. Verification of the implementation of these regulations/instructions and the direct supervision of resident veterinarians and inspectors is totally left up to the Team Leaders. Consequently, Regional Directors and District Heads are frequently unaware of improper or inadequate interpretation and implementation of FSIS HACCP, SSOP and other requirements.

In most cases, the supervision of the Regions by the Central office, the supervision of the Districts by the Regional office, and the supervision of the Teams by the District office is through the use of office meetings with specialty groups, management and supervisory personnel. Visits to supervised offices or supervised personnel by a supervising office is loosely organized and generally does not result in any documentation of the visit and the issues discussed. Audits for quality and process-controls assist in providing feedback to managers and supervisors. These auditors, however, do not have the authority to correct noted problems and do not accompany VIC during their audit of the establishments. Consequently, this system seems to rely on third party information to identify performance issues. There is very little over-the-shoulder supervision of the VIC and the Team Leaders. Follow up of problems identified by the Team Leaders or Auditors is relatively sporadic and unspecified by any CCA instructions or guidelines.

6.2.3 Assignment of Competent, Qualified Inspectors

Full-time, permanent CCA veterinarians possessing a Veterinary diploma resulting from a 6-year degree program are considered qualified to apply for the inspection service. During the coursework, veterinarians receive training in generic slaughter and processing operations. After being hired, they review appropriate training module(s) and are given some on-the-job-training (OJT), under the supervision of experienced veterinarians. Within a few months after being hired, each veterinarian takes two weeks of introductory training and six to eight weeks of internship where they learn about how to conduct inspections as a government veterinarian.

Private Practitioners, called Practitioners, are hired on a part-time basis for a maximum of 16 hours per week. These Practitioners usually belong to a Veterinary Clinic or have a clinic of their own and have the same diploma as the full-time CCA veterinarians. They are required to take the public health and/or animal health training modules that last 18 days before they begin work and are counseled on the difference between a private practitioner and a government veterinarian. They are advised to avoid any situations where a conflict-of-interest might occur and sign an employment contract that includes a confidentiality clause. Practitioners normally perform export inspections of live animals and ante-mortem inspection in slaughter operations and may also perform other RVV veterinary duties if they are properly trained. These practitioners are never assigned as a VIC or a Team Leader.

Full-time, permanent CCA meat inspectors must have successfully completed four years of vocational college training before they meat the minimum qualifications to become hired as a meat inspector. After they are hired, they must successfully complete nine months to one year of inspector training before they can work as a meat inspector in an establishment.

Full-time or part-time, 'temporary' assistant meat inspectors have completed four years of lower level vocational training before they meet minimum hiring qualifications. Assistant meat inspectors contract with a temporary hiring service and are hired through the service. After they are hired, they must successfully complete three to four months of inspector training before they can begin inspection duties.

6.2.4 Authority and Responsibility to Enforce the Laws

RVV has the authority and responsibility to enforce the applicable laws relevant to U.S. certified establishments. RVV not only has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not have adequate and/or effective controls in place to prevent, detect, and eliminate product contamination/adulteration. Establishments wishing to export product to the United States must write a letter to the Regional office serving the Province where the establishment is located. The Regional Director or Deputy Director then assigns either a Regional auditor or the appropriate District office the task of auditing the establishment and making a recommendation report to the Regional office. If approved, the recommendation is forwarded to the Central office for confirmation and U.S. notification. The Veterinarian-in-Charge and the Team Leader are responsible for working with the establishment and ensuring compliance.

The CCA is currently staffed by over 1600 employees. The Central office has approximately 220 employees with 24 in the veterinary services, eight in the instruction services, 10 in quality management, 10 in animal disease control, and 30 in inspection services. The rest are support personnel. Within these departments, there are approximately 48 veterinarians. In the field, veterinarians and inspectors ensure compliance with all applicable regulations and instructions in the 14 U.S. certified establishments. Within the Regions and Teams of the RVV, there are approximately 11 auditors. This number is projected to increase with the elimination of the chief meat inspector position (each Team having one or more of these employees). In fall of 2002, three new positions were created.

In addition, each of the five Regions is led by a Director and a Deputy Director, one of which is a veterinarian. Each Region also has four Specialists; one each in red meat, poultry, livestock, and live animal products, and one quality officer. Specialists are used to provide technical advice on regulations and instructions to field personnel. Each Region has two or more Districts that they supervise. Each of the 17 Districts has one District Head and two or more Team Leaders. The 48 Team Leaders are the first line supervisors for a group of establishments and are supported by the staff noted above and by the Veterinarian-in-Charge or senior meat inspector of each establishment. These offices and personnel were ultimately responsible for enforcing EC, FSIS, and Dutch legislation within the CCA and were directly responsible for regulatory compliance in U.S. certified establishments.

6.2.5 Adequate Administrative and Technical Support

During this audit, the auditors found that the CCA had begun applying resources to support more thorough and appropriate third party audits and in-house inspection reports.

In fall of 2002, CCA hired an out side consultant (NFC-Cook & Thurber) who held courses in SSOP and PR/HACCP for a selected group of Team Leaders and other inspection officials. CCA has also delivered internal training to a number of inspectors. However, everyone assigned to the U.S. approved establishments have not attended these training sessions. CCA is planning to conduct more such training sessions in 2003. At the Ministry level, the Netherlands has made some changes toward an overarching authority that has combined RVV and KvW into a new single food and non food authority (VWA). This new organization is part of Ministry of Health. However, any positive impact of these changes and any improvement in the government oversight of meat inspection in U.S. approved plants still remains to seen.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents and held interviews with officials at inspection headquarters in Voorburg, and at two regional and three district offices. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

Concerns arising as result of visits to these offices are recorded under government oversight section of this report.

6.3.1 Audit of Regional and District Inspection Offices.

As mentioned previously, two regional offices and three district offices were visited and interviews were held with following officials at locations indicated below:

Regional Department South (Helmond), Dr. J.P.J. Peelen, Deputy Director and
Regional Department East (Arnhem), Dr. J. Haverkort, Regional Director.
District heads of following three districts were interviewed:
District Office at Echt
District Office at Apeldoorn
District office at Hoogeveen

Since district offices are designated as front line offices, only auditor's reports were received at the regional offices. These reports are supposed to be sent to the District Heads. These reports were available only at one district office; the other two district

offices did not have these reports available. The auditor was informed that these reports are kept at the inspection office in the establishments. There is very little direct oversight provided to the Team Leaders in review of certified establishments. Two of the District Heads interviewed had not been fully trained in United States PR/HACCP and SSOP requirements. No documentation of observations made during establishment visits by the district personnel is maintained at district or establishment level.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of 10 establishments, six were slaughter establishments, two were processing establishments and two were cold storage. None of the establishments were delisted by CCA of the Netherlands. One establishment received a notice of intent to de-certify the establishment from the CCA of the Netherlands due to problems with SSOP and other sanitation deficiencies. This establishment may retain their certification for export to the United States provided that it corrects all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States' requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following laboratories were reviewed: LRVV Laboratory and Rikilt Laboratory, both located at Wageningen. LRVV analyzes all of microbiology and most of residue samples where as Rikilt laboratory does some of the residue analysis. Both of them are government laboratories.

Deficiencies observed are noted under Section 12 – Residue Controls.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, the Netherlands inspection system did not appear to have complete controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices. The following deficiencies were observed:

- Deficiencies were observed in nine of the 10 establishments.
- Three establishments had problems with maintenance and construction of equipment and utensils.
- Three establishments had deficiencies in construction and maintenance.
- Two had problems in areas of grounds and pest controls.
- In one establishment some problem were noted with use of sanitary equipment.

The Netherlands inspection system has controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, workspace, ventilation, welfare facilities, and outside premises.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in the 10 establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies noted in the implementation of SSOP:

- All 10 establishments had some deficiencies in implementation of SSOPs.
- Seven establishments had documented inadequate corrective actions in response to deficiencies.
- In five establishments some daily SSOP records were incomplete.
- Four establishments were not routinely evaluating effectiveness of SSOPs.
- Four establishments were not monitoring implementation of SSOPs
- Four establishments did not exhibit total control in use of insanitary equipment and operations.
- Two had deficiencies in areas of employee hygiene.

9.2 EC Directive 64/433

In nine establishments, the provisions of EC Directive 64/433 were not effectively implemented and some deficiencies were noted. Problems noted were in the areas of construction, maintenance, sanitation of equipment and utensils and in inedible controls. Specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that the Netherlands inspection system

had adequate controls in place. The following deficiency was noted in two establishments.

- Pens for segregation of suspects were not clearly identified and in one case, proper bedding and drinking water was not available.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the eight establishments (remaining two were cold storage facilities). Three establishments had adequately implemented the HACCP requirements while five establishments did not fully meet HACCP implementation requirements.

- Four establishments had not always documented corrective actions, as required.
- Four had inadequate frequency of HACCP verification and pre-shipment reviews.
- One had not reassessed its HACCP plan.

11.3 Testing for Generic *E. coli*

The Netherlands has adopted an equivalent *Enterobacteriaceae* testing program to the FSIS regulatory requirements for generic *E. coli* testing.

Six of the 10 establishments audited were required to meet the equivalent of the basic FSIS regulatory requirements for generic *E. coli* testing. These six establishments were

evaluated according to the criteria employed in the U.S. domestic inspection program or submitted by the CCA and determined equivalent by FSIS, as applicable.

The alternative, equivalent sanitary measures involve using *Enterobacteriaceae* instead of generic *E. coli* as an indicator organism, sampling based on a testing frequency of 10 tests per week rather than based on production, sampling swine from the flank, brisket, rump, and back rather than the ham, belly, and jowl, and using the cork-borer method of sample collection rather then the sponge or excision method.

Equivalent generic *E. coli* testing (i.e. *Enterobacteriaceae* testing) was properly conducted in five of the six slaughter establishments.

- One establishment did not randomly select carcasses for collecting the *Enterobacteriaceae* samples.

11.4 Testing for *Listeria monocytogenes.*

None of the 10 establishments audited were producing ready-to-eat products for export to the United States.

11.5 EC Directive 64/433

As noted in Section 9.2 above, in nine establishments, some provisions of EC Directive 64/433 were not fully implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. CLRVV and Rikilt laboratories, both of which are government laboratories, were visited.

The following deficiencies were noted:

First, CLRVV laboratory:

- *VIDAS* screening method was being used for screening of *Salmonella* samples.
- No *Listeria monocytogenes* samples from any establishment required to test for *LM* have been analyzed as yet. However, CLRVV is in process of validating a method. Both VIDAS and *LM* methods will be submitted to FSIS shortly for equivalence determination.
- All samples received are assigned an internal laboratory number for sample security purposes, however, original forms are left unsecured in the laboratory, thereby, defeating purpose of concealing information regarding origin of these samples.
- There is no program or procedure to check proficiency of individual technician for analysis of samples.
- Technicians are responsible for entering and "overriding" data changes, which has a potential of manipulation of some results.

Second, RIKILT laboratory:

- Some stock solutions had not been marked with sample preparation and expiration dates.
- No Nitrofuran samples had been analyzed. Check samples for this compound will be available and analyzed in 2003.

The Netherlands' National Residue Control Program for 2003 was being followed and was on schedule.

12.1 EC Directive 96/22

In the CLRVV and Rikilt laboratories, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the CLRVV and Rikilt laboratories, the provisions of EC Directive 96/22 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

13.1 Daily Inspection in Establishments

With the following exceptions, inspection was being conducted daily in all slaughter and processing establishments:

- There was inadequate documentation and lack of follow-up actions in several instances.
- Although inspection personnel are aware of HACCP requirements, many items such as verification for zero tolerance and independent verification of CCPs are not being adequately addressed. A new checklist is being developed by the CCA to bring uniformity in documentation.

13.2 Testing for *Salmonella*

The Netherlands has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s).

It had adopted using the cork-borer method of sample collection when sampling for *Salmonella* species under the PR/HACCP regulations. It is using alternative sampling procedures associated with the cork-borer method. Consequently, the depth of the excision, the size of the sampled area, and the compositing of the samples into a whirl-pack apply to the Netherlands' equivalence determination for *Salmonella* testing.

The alternative, equivalent sanitary measures involve using a continuous, on-going sampling program to determine when to initiate additional, targeted sampling for *Salmonella* rather than a sampling program based on production; sampling at the end of the slaughter or production process and prior to the carcass being cut and/or packaged rather than from chilled carcasses.

Six of the 10 establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the United States domestic inspection program or according to the alternative sanitary measures determined equivalent by FSIS, as applicable.

As noted above, the "Vidas" method is being employed instead of using ISO 6579 to analyze for *Salmonella* used by FSIS.

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit it was found that, with the following exceptions, in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented.

- Follow-up on deficiencies noted was not systematic and was frequently lacking.

Although some improvements had taken place since the FSIS review of June 2002, monthly reviews were still inadequate, covering only three areas of inspection. In many instances, monthly reviews were still not covering HACCP requirements. All areas of inspection need to be covered to some degree during each supervisory visit. These reviews were being performed by auditors from the Regional offices or by the Team Leaders. Access to these reviews varied. Non-inspection records, audit files, and U.S. certification documents were kept in the either the Regional or District office, depending on the Region. Team Leader supervisory reports and inspection records of certified establishments were usually kept in the inspection offices of the individual establishments. In the fall of 2002, the CCA had hired an outside consultant who conducted training in SSOP and PR/HACCP. In addition, CCA has conducted internal training courses. Both of these training programs were imparted to selected inspection officials leaving some key regional, district officials, team leaders and in-plant personnel still with lack of proper knowledge of FSIS' SSOP and HACCP programs.

13.5 Inspection System Controls

With the following exception, the CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

- In four establishments, condemned product was not being properly denatured. Product was being moved out of the processing rooms in to back yard for placing in the condemned tanks.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on February 12, 2003 in Voorburg, with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. M. Ghias Mughal
Chief, International Audit Staff

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Individual Foreign Laboratory Audit Forms
Foreign Country Response to Draft Final Audit Report

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 2-5-03

NAME OF FOREIGN LABORATORY: Laboratory of the Inspection Service for Livestock and Meat (LRVV)

FOREIGN GOV'T AGENCY: National Inspection Service for Livestock and Meat

CITY & COUNTRY: Wageningen, Netherlands

ADDRESS OF LABORATORY: Postbus 144 6700 AC Wageningen

NAME OF REVIEWER: Dr. M. Ghias Mughal

NAME OF FOREIGN OFFICIAL: Dr. Ron Dwinger, Mr. H.J. Kuekens, Head of Laboratory for Livestock and Meat

	Residue Code/Name ▶			200	203	500	800	923	Sal	Entb				
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01		A	A	A	A	A	A	A				
	Sampling Frequency	02		A	A	A	A	A	A	A				
	Timely Analyses	03		A	A	A	A	A	A	A				
	Compositing Procedure	04		O	O	O	O	O	O	O				
	Interpret Comp Data	05		O	O	O	O	O	O	O				
	Data Reporting	06		A	A	A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A				
	Correct Tissue(s)	08		A	A	A	A	A	A	A				
	Equipment Operation	09		A	A	A	A	A	A	A				
	Instrument Printouts	10		A	A	A	A	A	O	O				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O	O	A	A	A	O	O				
	Recovery Frequency	12		O	O	A	A	A	O	O				
	Percent Recovery	13		O	O	A	A	A	O	A				
	Check Sample Frequency	14		A	A	A	A	A	A	A				
	All analyst w/Check Samples	15		A	A	A	A	A	A	A				
	Corrective Actions	16		A	A	A	A	A	A	A				
	International Check Samples	17		O	O	O	O	O	O	O				
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O				
OTHER REVIEW		19	EVAL. CODE											
		20												

SIGNATURE OF REVIEWER: for Ghias Mughal

DATE: 2/5/03

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 2-6-03

NAME OF FOREIGN LABORATORY: State Institute for Quality Control of Agricultural Products (RIKLIT)

FOREIGN GOV'T AGENCY: Department of Wageningen University and Research Center (WUR)

CITY & COUNTRY: Wageningen, Netherlands

ADDRESS OF LABORATORY: Building No. 123 Bornesesteeg 45, Wageningen

NAME OF REVIEWER: Dr. M. Ghias Mughal

NAME OF FOREIGN OFFICIAL: Ms. Celia Steegman, Mr. A. Roos, Department of Assurance

	Residue Code/Name ▶			100	111	300	400	500	600						
	REVIEW ITEMS	ITEM #													
SAMPLING PROCEDURES	Sample Handling	01	EVALUATION CODE	A	A	A	A	A	A						
	Sampling Frequency	02		A	A	A	A	A	A						
	Timely Analyses	03		A	A	A	A	A	A						
	Compositing Procedure	04		O	O	O	O	O	O						
	Interpret Comp Data	05		O	O	O	O	O	O						
	Data Reporting	06		A	A	A	A	A	A						
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A						
	Correct Tissue(s)	08		A	A	A	A	A	A						
	Equipment Operation	09		A	A	A	A	A	A						
	Instrument Printouts	10		A	A	A	A	A	A						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A						
	Recovery Frequency	12		A	A	A	A	A	A						
	Percent Recovery	13		A	A	A	A	A	A						
	Check Sample Frequency	14		A	A	A	A	A	A						
	All analyst w/Check Samples	15		A	A	A	A	A	A						
	Corrective Actions	16		A	A	A	N	A	A						
	International Check Samples	17		A	A	A	A	A	A						
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O						
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER: [signature] Ag. Chief Mission

DATE: 2/6/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco Lichtenvoorde B.V. Lievelde	January 22, 03	60	Netherlands
5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT	
Dr. M. Ghias Mughal		X ON-SITE AUDIT	DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan.	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	X
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	X
48. Condemned Product Control	X
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	X
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 60 Date of Audit. January 22, 2003

12. Sole sterilizer in a large boning room intended for cleaning contaminated knives, steel gloves and any other items that may become contaminated with condemned material (SRM-Specific high risk material) was not conveniently located. Two other sterilizers in the cutting room were also not conveniently located for employees to sanitize equipment.

13/19. Sanitation and HACCP monitoring/verification were combined in one checklist and is not clearly defined. QA supervisor was unable to clearly differentiate between SSOP and HACCP procedures. No follow-up action had been documented on the sanitation deficiencies noted.

19. Pre-shipment review was not being done as required. Pre-shipment checklist did not account for CCPs 3 and 4.

20. Corrective action for CCP deviations does not meet requirements of FSIS Regulation 417.3

28. *E. coli* (*Enterobacteriacae*) sampling is not random. Samples are taken at the convenience of the employees.

45 Equipment (plastic product tubs, meat hooks and some other equipment) is stored outside in the back of the building where it is cleaned, sanitized and rinsed prior to use.

47. Employees cover street clothes with smocks and aprons inside the plant but then have to walk out of the building to go into some work areas because of lack of covered space.

48 Condemned product (SRM material) is moved outside the building without proper denaturation. Denaturation is done Near an inedible storage tank located on back side of the building.

54. Suspect pen was not properly identified.

Plant was placed on the NOIE list by the government officials.

61. NAME OF AUDITOR
Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE
1/23/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO	4. NAME OF COUNTRY
Dumeco Weert B.V. Weert	January 23, 03	64	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific evert occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 64 Date of Audit. January 23, 2003

10. Some clean steel gloves had fat particles (residues from previous day's operation). Some ham hooks had fat and blood residues. One cutting board had rough, scored areas. Red plastic crates used for meat had fat residues and one was cracked at the bottom.

11. Pre-operational and operational programs were not completely separated and establishment officials did not fully understand the SSOP program. Some records were contradictory. One checklist showed no condensation observed while other on the same day recorded condensation in the facilities.

12. In the parts cooler, condensation was observed in certain locations. Also, the carcass chiller had some condensation on the rails.

19. Verification frequency for CCPs 2 and 4 was inadequate and it was not done at random times.

38. In the dry storage room, a roll of plastic film was on the floor and there were cobwebs in corners and on the wall behind the boxes.

51. Several on- going deficiencies had been noted both by establishment and inspection officials. Most establishment checklists showed no condensation problem, which seemed to have been removed by wiping. Plant also had documentation for planned improvement and changing of airflow in next two months. However, inspection daily reports showed no condensation issues.

RVV had not done any independent verification of CCP 2. The Team Leader did not seem to understand the HACCP Program. CCP1 (fecal tolerance) - Inspector's verification had noted one carcass with fecal contamination. However, instead of taking regulatory action, inspectors were checking another 50 carcasses and would notify the establishment when a second sample showed a carcass with feces.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

1/23/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco Scherpenzeel B.V. SchrtpenzeeL	January 29, 03	82	Netherlands

5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT
Dr. M. Ghias Mughal	[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 82 Date of Audit. January 29, 2003

11. Some clean, ready to use, red plastic tubs and one steel combo bin in the boning area had fat residues on product contact surfaces.

12. The procedure demonstrated for sanitization of dirty equipment was inadequate. Reconditioning of dirty meat was done correctly. However, the procedure did not clearly demonstrate cleaning of dirty steel gloves and cutting boards. There was only one inconveniently located sterilizer in the bacon room.

20. Each hook during unloading of carcass parts from the trucks was being monitored for fecal as per the HACCP Plan. On deviation, corrective action recorded is trimming of affected part. No further action is taken until 5 parts are found to be contaminated which does not meet FSIS 417.3 requirements.

45. In the boning room, the meat-reconditioning table was not clearly identified and light intensity was less than required. There was excessive grease on some rails in one holding cooler.

47. During company break, one employee walked out of the bathroom without washing hands. Some other employees clothes were not fully covered.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hendrix Meat Group C.V. Emmen	January 20, 03	160	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	X
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	X
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	X
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 160 Date of Audit. January 20, 2003

12. In the large deboning room, both sterilizers were inconveniently located for the employees to sterilize knives, steel gloves and equipment.

13. Deficiencies were being identified during pre-operation monitoring. However, follow-up actions in many instances were not being documented.

39. Excessive grease was observed on a chain sprocket in use in the expedition area. Also, some rails had dust and rust.

44. There were no hooks outside the toilet located near freezer for employees to hang their coats and /or tools.

48. Containers used for the inedible (SRM) product were not properly identified.

51. Documentation of the corrective action taken by the establishment of problems identified on monthly reviews was incomplete. Problems had been identified on many monthly inspection reviews, however, deficiencies noted had been left open for many months. Follow-up inspection, if taken by inspectors, is inadequate.

54. Suspect pen was not identified in the ante-mortem area. Area identified as suspect pen by the establishment officials had no water supply.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO	4. NAME OF COUNTRY
Hendrix Meat Group C.V. Meppel	January 30, 03	193	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	X
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No.193 Date of Audit. January 30, 2003

10. Some livers in organ cooler were touching a wall; also small fat particles of residue from previous day's operation were observed inside a few washed red plastic crates.

12. Some beaded condensation in cooler, under a refrigeration unit and on a pipe by the entrance in the organ cooler, above exposed product was observed.

19. Pre-shipment verification documentation is not done as required.

21. Corrective action on CCP 1 did not meet all the FSIS 417.3 requirements. *Repeat deficiency from last fall.*

21. HACCP Plans had extra CCP that did not conform to the operation of the establishment.

45. Reconditioning table used for contaminated meat did not have conveniently located facilities for washing hands and for sanitizing equipment.

46. In cutting room, one bottle containing inedible dye had been left on a clean cutting table.

51. Government Inspectors did seem to understand FSIS HACCP requirements. No follow actions had been documented on many previously identified deficiencies. CCP verification times selected by RVV were not random.

This establishment is to be delisted, as per a checklist review by FSIS.

61. NAME OF AUDITOR
Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE
1/30/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hendrix Meat Group C.V. Druten	January 24, 03	236	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		X ON-SITE AUDIT ☐ DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan.	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific evert occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 236 Date of Audit. January 24, 2003

10. In boning room, some green cutting boards had rough areas and were deeply scored.

11. In the packaging room, one plastic crate containing tenderloins was sitting under the plastic bag used for collecting trash. Bottom of the bag was touching the meat.

12. In the Shipping Area, some slightly beaded condensation on rail, under a refrigeration unit above exposed product. Also, in middle of holding cooler, there was slight condensation under a refrigeration unit. Sole sterilizer and hand washing station in the boning room were not conveniently located.

13. Establishment's sanitation checklists had documented deficiencies noted during sanitation checks. However, time observations and corrective actions were not documented.

19. CCP verification frequency was inadequate.

20. Corrective action for CCP deviation did not document any preventive action.

38. Plastic curtain on the overhead shipping door was torn in one area and door did not close properly, leaving a gap in the bottom.

51. Government Inspectors did not document any enforcement actions taken as required.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. M. Ghias Mughal	1/24/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco Apeldoorne B.V Apeldoorne	February 3, 03	312	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific evert occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	X
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 312 Date of Audit. February 3, 2003

11. Heavily beaded condensation was observed in corridor which was in use for moving carcasses from kill floor to the cooler; also some lightly beaded condensation on ceiling of a truck being loaded.

10. Product transfer belt in the boning room had deep cuts and cracks. A roll of plastic was touching a wall in the dry storage room next to the boning room.

48. Inedible product is not denatured prior to moving it to the storage tank outside the building.

51. Inspectors did not maintain records for non-compliance of zero tolerance when deviation is observed during verification of zero fecal tolerance.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

2/3/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco Doetinchem B.V Doetinchem	January 21, 03	404	Netherlands
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. M. Ghias Mughal	[X] ON-SITE AUDIT	[ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific evert occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	X
48. Condemned Product Control	X
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 404 Date of Audit. January 21, 2003

11. Several clean ready to use plastic baskets (tubs) had fat particles and black residue on the inside product contact surfaces. One large gray plastic combo tub had rough, frayed areas.

12. There was not enough water in the sterilizer, located in the receiving area, to completely submerge the knife blade. The only sterilizer in the processing room was not conveniently located.

39. There was excessive grease on the rails in the receiving cooler.

47. Some employees had not covered their heads properly; and some others' street clothes were not fully covered.

48. One inedible container used "Low Risk Material" was not properly identified.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

1/21/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO	4. NAME OF COUNTRY
Koel-en Vrieshuis Lintelo B.V. Lichtenvoorde	February 4, 03	451	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 451 Date of Audit. February 4, 03

13. Daily pre-operational and operational deficiencies were not clearly separated. Time when deficiencies were noted and corrected had not been documented.

39. Plastic curtains at the entrance of several frozen belly packing rooms had accumulation of black residue; some were torn.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

2/4/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Lau Van Haren Weurt	January 31, 03	584	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. M. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands - Establishment No. 584 Date Of Audit. January 31, 03

13. Daily pre-operational and operational deficiencies were not clearly separated. Time when deficiencies were noted and corrected had not been documented.

51. Documentation of deficiencies noted by the government inspector was not specific and documentation of any follow-up action taken by the establishment was inadequate.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

1/31/03

Ministerie van Landbouw, Natuur en Voedselkwaliteit

Ministry of Agriculture, Nature Management and Fisheries

United States Department of Agriculture
Food Safety and Inspection Service
Dr S. Stratmoen
International Equivalence Staff
Office of International Affairs
Washington D.C. 20250
Fax: 00 202 690 4040

landbouw, natuur en voedselkwaliteit

c.c.: Dr A. Checchi Lang, DG Sanco

Your letter of	your reference	our reference	date
19-05-2003		VVA 03.2112/cs	14-07-2003
re:		extension no.	enclosures
Response to draft audit report January-February 2003		00 31 70 3784 356	

Dear Dr Stratmoen,

In this letter, I set out the Dutch response to the draft audit report on the Dutch Meat inspection system carried out by the FSIS in the Netherlands from 15 January to 12 February, 2003. A copy of this letter will also be sent to the European Commission.

In our teleconference on 8 April, I informed you that I was pleased with the findings of Dr Mughal; no establishments were delisted and only one establishment had received a 30-day notice. Compared to the previous audits, the findings were more positive and the remarks given concerned mostly minor details. It was therefore a very unpleasant surprise that the main findings in the audit report were very negative in tone and that none of the efforts made by us in the previous months were mentioned. For that reason, this letter not only includes the list of measures taken after this last audit but also the actions taken previously. I assure you that I take the auditor's comments and yours very seriously, but I also feel that we should be working according to a system of equivalence for safety standards for meat and meat products in the United States and the Netherlands, and by extension the European Union. I will ask the European Commission to help us to realize a system of equivalence.

The next audit, scheduled for the end of August, will offer an opportunity to demonstrate that the Netherlands is making good progress in fulfilling the United States demands on exported meat and meat products. I hope, however, that on the basis of the corrective measures taken by us, see below, and our letter of 27 March 2003 (reference number VVA 03.1019) you will be able to decide to revoke the enforcement actions before the start of this next audit,.

General remarks

1. On 30 January 2003, the American auditor inspected slaughterhouse no. 193 (EC code) in Meppel. After an extensive inspection, the auditor declared to all those present that the establishment fulfilled all requirements and could again be placed on the list of certified establishments. The Dutch authorities were therefore highly surprised when this decision

Ministry of Agriculture, Nature Management and Fisheries
Directie Voedsel en Veterinaire Aangelegenheden
Veterinaire Handel en Controle
Bezuidenhoutseweg 73
Postal Address: 20401
2500 EK Den Haag
Telephone: 070 - 3784 356
Fax: 070 - 3786 389

2. The enforcement actions announced by the FSIS in its letter of 28 March 2003 are quite severe and do not bear relation to the nature of the shortcomings stated in the audit report. According to the report, none of the establishments certified to export meat and meat products to the United States were delisted on the basis of these shortcomings (page 13, point 7).

3. I regret the overall negative tone of the report, stressing errors and shortcomings and paying scant attention to the actual and rapid progress made in the brief period between the June 2002 audit and the January 2003 audit. These improvements include training activities and monthly reports by the heads of team. I would like to remind you that I also objected to the overall negative tone of previous reports, concerning the June 2002 and 2001 audits.

4. I find that the audit report contains colored phrasing and generalizations (some inspectors, lack of inspection, inadequate training, had problems, had deficiencies, etc.). The auditor's remarks concerned minor details, but the way the report is worded gives a very different impression.

5. According to your letter of 28 March, 2003 FSIS is concerned about the level of governmental supervision in the Netherlands' inspection system. I would suggest placing more emphasis on this matter in the next audit. I have noticed that, in every audit report, questions are raised by the FSIS about our supervisory structure. Every time we have tried to explain the structure, but I think that more clarification still is needed as regards the organization of the inspection system in the Netherlands. Perhaps more time should be spent discussing the systems in both countries to see if equivalence exists, instead of demanding that we copy the US system (which would be impossible from a systematic point of view).

6. In view of the Veterinary Equivalence agreement[1] it is remarkable that during the audit the HACCP program was evaluated on the basis of criteria for the United States domestic inspection program.

Specific remarks

- page 8, second paragraph, first sentence: Contrary to what the report claims, there are four (not three) levels within RVV: central, regional, district and team. We refer to this as the "four chiefs system".
- page 8, second paragraph, 16th line: Twenty-six veterinarians and 150 inspectors are available for 14 establishments which are certified for export to the United States.
- page 9, first paragraph, last sentence: An extensive three-week training program has been set up for three specialized positions: meat inspector, control and audit officer, technical administration officer and senior meat inspector.
- page 9, third paragraph: voluntary surrendering of the certified status resulted in a reduction in the number of certified establishments. One establishment was delisted by RVV because it did not meet the requirements; four voluntarily surrendered their certification.

- page 9, 6.2.2, fifth line: the implementation of a uniform, standardized approach for the control of observed shortcomings by regional and district heads has started (see the section "Measures taken").
- page 9, 6.2.2, second paragraph, first and second lines: the equivalence agreement between the European Union and the United States allows for another approach. Agreements for product groups falling under this agreement are made unilaterally, not bilaterally.
- page 9, 6.2.2, second paragraph, tenth line: "Regulations are rarely compared to checklists that are developed at the lower levels for specific purposes". In the previous line, the report states that most checklists are developed by the RVV central office on the basis of current regulations. RVV officials are required to follow RVV orders, including use of the checklists. In other words, the checklists do not need to be checked, but are adapted when the regulations are amended.
- page 9, 6.2.2, last line on the page: more than before, regional and district heads will be involved in controlling the observed shortcomings at establishments (see the section "Measures taken").
- page 10, first sentence: The systematic involvement of regional and district heads has been arranged (see previous point and the section "Measures taken").
- page 10, second paragraph: supervision of heads of team will be improved. Effectiveness will be assessed by the Quality Management Section in June 2003.
- page 10, second paragraph, seventh line: "These auditors do not have the authority to correct noted problems and do not accompany VIC during their audit of the establishments". This is not correct. The auditor notes problems, but the veterinarian bears the primary responsibility for ensuring that improvements are made. This is consequently verified by the team and district heads, and if necessary by the regional director. The verification structure will be improved.
- page 10, 6.2.3, first paragraph: officially the veterinary degree program in Utrecht lasts six years, not five, but it takes most students longer to qualify due to a shortage of intern positions at veterinary practices.
- page 10, 6.2.3, first paragraph: the training module for "CCA veterinarians" has a duration of three months.
- page 10, 6.2.3, second paragraph: please add that the training modules for "Practitioners" has a duration of 18 days.
- page 11, 6.2.4, third paragraph: the term "inspector in charge" is somewhat misleading. It would be more appropriate to use the term "senior meat inspector" here.
- Page 12, first paragraph: I ask that you follow up the remark that not everyone took part in the training course for export to the US with the following: "Thirty people, including 22 veterinarians, followed the training course organized by NFC-Cook & Thurber. Not everyone working at a US-certified establishment was able to follow the course (in part because it was given in English), but most of the veterinarians working at such establishments did attend. The course will be repeated later in the year, in Dutch, so that other RVV employees can also take the course. A separate training course was developed by NFC-Cook & Thurber for the staff of the certified establishments themselves."
- Page 12, point 6.3.1: the regional office is located in Apeldoorn (not Appledorn).
- Page 13, first paragraph, 3rd sentence: CCA's objective is to train people on the work floor first, and then management.
- Page 13, point 7: "*None of the establishments were delisted by the CCA of the Netherlands nor by*

- Page 14, third paragraph: *"The Netherlands inspection system, however, did have controls in place..."*. I find this phrase very negative and suggest rephrasing it: *"The Netherlands inspection system has controls in place..."*.
- Page 16, second paragraph: *E. coli* sampling by the establishment is based on the number of slaughtered pigs, specifically 1 sample per 1000 pig carcasses (thus reflecting production). Sample collection is carried out in accordance with Commission Decision 2001/471/EC and has been declared equivalent by the FSIS, as confirmed by point 11.3 on page 15. Initially, the samples were all taken at once at the same time of day. During the audit, it was noted that the production process could be better controlled by spreading sample collection over the day. This change has been incorporated in the latest version of working orders for RVV staff (RE-31). RVV shall verify that samples are collected correctly.
- Page 17, point 13.1, second bullet: The checklist was developed at the auditor's recommendation in order to increase the uniformity of the reports. RVV staff training commenced in November 2002, in English, and will be repeated later this year, in Dutch, for a second group (same number of employees). See also the section "Measures taken". This information was also given at the time of the audit. I therefore find the phrase *"inspection personnel still are not sure of all HACCP-requirements..."* both inaccurate and colored. I assure you that staff are well aware of all HACCP-requirements.
- page 18, point 13.4: The conclusion "all of these were repeat findings" is incorrect. The recommendation for training in the previous audit report was followed up. Reports by the heads of team are drawn up every month and were available at all establishments. RVV will monitor the uniformity of the reports. In addition, the heads of team will be instructed to evaluate "all areas of inspection to some degree".

Measures taken

- Evaluation with the establishments concerned regarding the results of the American audit and the improvements to be made.
- Evaluation with RVV staff (veterinarians, heads of team, meat inspectors, district heads and auditors) at the district offices regarding the results of the American audit and the improvements to be made. Extra attention was given to the daily control activities, an accurate report of findings and regular controls by senior staff.
- One establishment has been informed in writing that compliance is required at all times, irrespective of whether meat is being exported to the United States.
- One establishment did not satisfy all requirements at the time of the FSIS audit. This establishment was inspected by RVV staff after thirty days to ensure that all shortcomings had been repaired. The audit report has been sent to you in Dutch and English.
- After having validated the assay method for *Listeria monocytogenes,* the RVV laboratory commenced sampling of meat processing establishments which make ready-to-eat products. A sampling order was written for employees on the work floor (RE-34). The assay method is laid down in SOPO32, in accordance with ISO 11290-2 1998 requirements.
- A new Laboratory Management Information System (version LIMS-4) has been implemented in all the RVV laboratory teams. This system prevents unauthorized data changes using the audit trail function.
- Laboratory staff test samples which are identified by a unique code. Staff do not know where the samples were taken. The team head keeps the accompanying sample forms

- The RVV laboratory has implemented a comprehensive quality assurance system. The system comprises: control samples made by the lab technician (first line); control samples made by the head (second line); and anonymous samples obtained from the National Reference Laboratory (third line).
- The RVV laboratories have adopted a new screening method for Salmonella in biological samples (VIDAS system). This method has been validated in house and accredited for ISO 17025. A copy of this method was given to the auditor on 5 February 2003. The ISO method is still used to reconfirm positive cases.
- Changes to order RE-31: entry requirements for establishments wishing to export meat and meat products to the United States. The following additions or revisions were made to the text:
    - Increased control by regional heads on the shortcomings and points for improvement observed by team heads according to a uniform and standardized approach.
    - More comprehensive, more intensive internal audit by the Quality Assurance section (Afdeling Kwaliteitsmanagement). Internal audits will focus on controlling the effectiveness of RVV supervision at US-certified establishments.
    - The monthly reports by team heads regarding day-to-day control of US-certified establishments are standardized. A verification form has been printed as a guide.
- Training for all RVV staff working at US-certified establishments. Training courses consist of:
    - A half-day of practical and theoretical training in the collection of carcass samples for *Salmonella* en *E.coli*.
    - Three days of instruction in HACCP, SSOP and enforcement. This course is being organized for about thirty staff members in October-November 2003 and is a repeat of an earlier course organized by an equal number of RVV staff in November 2002.

In summary, I urge you to recognize the efforts of the Dutch CCA and the meat industry to produce and export products of the highest standard. I would like to discuss with you the possibilities of working on the system of equivalence. The measure taken in response to the last audit, on top of all the improvements of the past few years, demonstrate that we are doing everything we can to repair all deficiencies. There is no doubt in my mind that we have made a lot of progress and I hope that you also share this opinion. I am depending on it that my remarks regarding this audit report will be incorporated in the final report.

Yours sincerely,

CHIEF VETERINARY OFFICER

Dr F. Pluimers